

## **REMARKS**

The Office Action dated July 11, 2007 has been carefully considered. Claims 1-23, 25 and 26 are pending. Claims 1, 25 and 26 have been amended to clarify certain embodiments of the presently claimed invention. Support for the amendments can be found in the originally-filed specification at, *inter alia*, page 6, lines 30-31. No new matter has been added.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

### **I. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)**

#### **A. Claims 1-4, 7-20, 22-23 And 25-26 Are Patentable Over Pagedas In View of Benecke**

Claims 1-4, 7-20, 22-23 and 25-26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,221,384 to Pagedas ("Pagedas") in view of U.S. Patent No. 5,008,110 to Benecke *et al.* ("Benecke"). For the following reasons, Applicant respectfully disagrees.

Independent claims 1, 25, and 26, as amended, recite methods of delivering a drug (claims 1 and 25) or a narcotic analgesic (claim 26) through a patient's skin using a transdermal delivery system comprising a plurality of patch units, wherein each patch unit comprises a backing layer having one or more borders, a drug layer comprising a drug disposed on the backing layer, and an adhesive layer, wherein the borders of the backing layer are free of any drug, and wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer. The plurality of patch units are connected to each other along one or more borders of the patch units; and each patch unit is defined by one or more lines of separation along the borders of the patch units. The method includes the steps of separating at least one patch unit from the transdermal delivery system along at least one line of separation; and applying at least one patch unit such that the drug layer makes contact with the skin.

Pagedas does not teach or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the borders of the backing layer, wherein the borders are free of any drug, as recited in amended claims 1, 25 and 26, respectively. In addition, Pagedas does not disclose or suggest a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer as recited in amended claim 1, buprenorphine as recited in amended claim 25, or a narcotic analgesic as recited in amended claim 26.

Benecke does not remedy the deficiencies of Pagedas. First, unlike the presently claimed invention, Benecke is not even directed to a transdermal delivery system comprising a plurality of patch units. In particular, Benecke does not disclose or suggest a plurality of patch units that are connected to each other along one or more borders of the patch units, wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims.

Second, Benecke also does not teach or suggest a patch unit having a drug layer disposed on a backing layer and a portion of an adhesive layer disposed on the borders of the backing layer, as recited in the present claims. In fact, Benecke teaches away from a drug layer disposed on a backing layer, as recited in amended claims 1, 25 and 26. The drug reservoir in Benecke is not disposed on the backing layer. Instead, the drug reservoir of Benecke is encapsulated within a hermetically-sealed compartment (see, *e.g.*, Abstract; Figs. 2 and 6). Benecke discloses that such structure prevents the drug formulation from contacting adhesive (Abstract). As such, one skilled in the art would not find suggestion or motivation in Pagedas or Benecke to modify or combine the teachings of these references to obtain the presently claimed invention.

Accordingly, amended claim 1 and its dependent claims, and amended claims 25 and 26, are believed to be patentable over Pagedas in view of Benecke. Thus, withdrawal of this rejection and allowance of claims 1-4, 7-20, 22-23, and 25-26 are respectfully requested.

**B. Claim 5 Is Patentable Over Pagedas In View Of Benecke And Further In View of Miranda**

Claims 5 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pagedas in view of Benecke and further in view of U.S. Patent No. 5,091,186 to Miranda *et al.* ("Miranda"). Specifically, the Examiner asserts that it would have been obvious to incorporate a rate limiting releasing agent into the drug layer based on the teachings of Miranda (see page 5). For the following reasons, Applicant respectfully disagrees.

Claim 5 depends from amended claim 1 and further recites that the transdermal delivery system comprises a release limiting layer disposed on the drug layer. For the reasons discussed above in connection with amended claim 1, claim 5 is also believed to be patentable over Pagedas and Benecke.

Miranda does not cure the deficiencies of Pagedas and Benecke. Like Benecke, Miranda also does not teach or suggest a patch unit wherein at least a portion of the adhesive

layer is disposed on the borders of the backing layer, wherein the borders are free of any drug, as recited in amended claim 1. In fact, Miranda, like Benecke, does not even disclose or suggest a transdermal delivery system comprising a plurality of patch units comprising a backing layer having one or more borders, wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims. Furthermore, Miranda does not disclose or suggest a release limiting layer disposed on a drug layer, as recited in claim 5.

One skilled in the art would not find motivation in Pagedas, Benecke, or Miranda to combine the teachings of these references to obtain the presently claimed invention, particularly where Benecke teaches away from a drug layer disposed on a backing layer of the patch unit, and Pagedas and Miranda do not disclose or suggest an adhesive layer disposed on the borders of a backing layer, wherein the borders are free of any drug.

As such, the rejection is believed to be in error and should be withdrawn. Accordingly, claim 5 is believed to be patentable over Pagedas, Benecke and Miranda.

**C. Claim 6 Is Patentable Over Pagedas In View Of Benecke And Further In View of Campbell**

Claims 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pagedas in view of Benecke and further in view of U.S. Patent No. 4,460,372 to Campbell *et al.* ("Campbell"). Specifically, the Examiner alleges that Campbell discloses a transdermal patch comprising the encapsulation of the active drug in microcapsules (see page 6). For the following reasons, Applicant respectfully disagrees.

Claim 6 depends from amended claim 1 and further recites that the drug is encapsulated by microcapsules. For the reasons discussed above in connection with amended claim 1, claim 6 is also believed to be patentable over Pagedas and Benecke.

Campbell does not cure the deficiencies of Pagedas and Benecke. Campbell, like Benecke, also does not disclose or suggest a plurality of patch units wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, and the step of separating at least one patch unit from the transdermal delivery system along at least one line of separation, as required by the present claims.

Furthermore, Campbell does not disclose or suggest a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer as recited in amended claim 1. Also, Campbell does not teach or disclose a drug encapsulated by microcapsules, as the Examiner has asserted, but

rather percutaneous absorption enhancers encapsulated by microcapsules (see, *e.g.*, Fig. 3, col. 7, lines 7-11).

One skilled in the art would not find motivation in Pagedas, Benecke, or Campbell to combine the teachings of these references to obtain the presently claimed invention, particularly where Benecke teaches away from a drug layer disposed on a backing layer of the patch unit, and Pagedas and Campbell do not disclose or suggest (1) a narcotic analgesic, a local anesthetic, a sedative, or a tranquilizer and (2) a patch that comprises such drug encapsulated by microcapsules.

As such, the rejection is believed to be in error and should be withdrawn. Accordingly, claim 6 is believed to be patentable over Pagedas, Benecke, and Campbell.


## II. CONCLUSION

Thus, as the claim rejections are believed to be overcome, the pending claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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